UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Michelle Simha, as Trustee for the Next-of-Kin of Noah Leopold, Plaintiff, vs. Mayo Clinic, Defendant.	Civil File No. 24-CV-01097-DTS

Plaintiff's Memorandum of Law in Support of Her Motion to Amend to Add a Claim for Punitive Damages (Filed Under Temporary Seal)

Introduction

This is one of the most extraordinary malpractice claims Plaintiff's counsel has handled in nearly twenty years of practicing law. After promising a young heart transplant patient named Noah Leopold that he had "the luxury of time" to wait for the "perfect" donor heart, the Mayo Clinic instead tried to transplant the heart of a convicted felon, drug-addicted, pack-and-a-half a day smoking former alcoholic with a prior history of heart surgery who used meth regularly and died with a half-dozen illicit drugs in his system. Despite Mayo's explicit promise to Noah that it wouldn't accept the heart of a donor who had died of a drug overdose, Mayo knew full well this donor had in fact died of a meth overdose.

Mayo concealed all this information from Noah and his family. Instead, Mayo told Noah his new heart was coming from an "excellent donor."

The heart was brought from the other side of the country, using novel technology known to have serious problems. But despite knowing that about one out of every six hearts transported on this technology end up not being transplantable, Mayo planned to remove Noah's heart before the donor heart arrived.

Mayo concealed this from Noah and his family as well. In fact, Mayo actively led them to believe the opposite – that the donor heart would be inspected in the operating room before any irreversible steps were taken.

The donor heart was supposed to be constantly monitored during transport. But the two surgeons charged with that responsibility [redacted]

When the heart arrived in the operating room, the surgeon noticed it was bruised and too big. But with Noah's heart already irreversibly removed and sitting on a back table, there was no choice but to go forward with the surgery.

He had to "make the heart fit," and hope it wasn't one of the one-in-six that failed.

Unfortunately, it was. During the transplant the heart began to "fall apart" and "bleed uncontrollably." The surgeons tried for hours to stop the bleeding, but were unable to do so. They had to remove the diseased donor heart, leaving Noah with no heart whatsoever. He was put on a bypass setup in the hopes he could recover in time to get another, better heart.

It didn't work. Noah deteriorated over the course of the next 10 days, and despite eventually getting another heart he passed away. He left behind his wife, parents, sister, and nephews.

Noah's family was equal parts devastated and perplexed by his death. Though he needed a heart transplant, his underlying health was good. He took excellent care of himself, riding an exercise bike for hours even while in the hospital waiting for his transplant. Noah's family could not understand how the "perfect" heart from an "excellent donor" could have catastrophically fallen apart as it did – and Mayo was offering them few (if any) answers.

So Noah's family retained counsel to investigate. And it quickly became apparent that the real story of what had happened to him was far different from what Mayo had led them to believe. They learned Mayo had actively misled Noah about many critical facts, and knowingly concealed many others. And they

learned that this tragedy stemmed from Mayo's concerted effort to radically increase the number of heart transplants it performs, in order to improve its standing in the transplant community.

As outlined below, the extraordinary facts of this case demonstrate deliberate indifference to Noah Leopold's rights and safety. Punitive damages are therefore appropriate.

Factual Background

A. Mayo's Heart Transplant Program

While Mayo Rochester has for years had some of the premier solid-organ transplant programs in the country, its heart transplant program has traditionally lagged far behind institutions of comparable prestige. As recently as 2021, Mayo Rochester's heart transplant program was ranked just 40th in the nation in outcomes and volume. Villavicencio Dep., 6:15-7:12.

In 2021, however, Mayo Rochester brought on a new director for its heart transplant program: Dr. Mauricio Villavicencio. *Id*., 7:4-6. Within just a few years' time, the program had dramatically increased its transplant numbers. *Id*. One of the ways it did so was by accepting hearts that other institutions would not. Indeed, Mayo's marketing department instituted a slogan that captured this new approach: "when others say no, we say yes." *Id*., 17:25-18:24.; *see also*

https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-transplant-programs-achieve-record-volumes-in-2023/.

This new approach worked, at least in terms of increasing transplant volume (one of the key measures of "success" of a program). In early 2024 Mayo trumpeted that its heart transplant program had achieved "record volumes" in 2023. *Id*.

To achieve these record numbers, Mayo[1] accepted donor hearts that other institutions simply wouldn't touch. According to the most recent data from the Scientific Registry of Transplant Recipients ("SRTR")[2], Mayo accepts high risk donor hearts at an almost astonishing clip. This includes donor hearts at risk of viral infection (more than two-and-a-half times the national average), with impaired pumping function (more than twice the average), from donors over the age of forty (more than three times the average), hearts considered "hard to place" (nearly four times the average), and hearts from more than 500 miles

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[1] The Mayo Clinic has three locations that perform heart transplants: Rochester, Jacksonville, and Phoenix. Because the care at issue here involves only Rochester, except where otherwise noted the use of "Mayo" herein should be taken to refer to Mayo Rochester.

[2] SRTR is the repository for virtually all transplant-related statistics in the United States. https://www.srtr.org/about-srtr/mission-vision-and-values/. When transplant programs tout their "statistics," they are referring to the SRTR data.

away (nearly twice the average). Ex. I[3] (SRTR Data Report) at 18; *see also* Villavicencio Dep., 18:25-20:14).

Broadening the pool of available donor hearts is an admirable goal – to a certain extent. When a loved one is on death's door, having the option to at least try a Hail Mary with a marginal heart can be a godsend. But there is a dark side to this as well. After all, there is a reason "others say no" to all these extra donor hearts Mayo is transplanting – they are objectively more risky than less marginal hearts. It is one thing for the transplant program to decide it is willing to take these additional risks. It is quite another for the program's doctors to actively hide those additional risks from patients and their families, thereby depriving the patient from being able to make an informed decision about his or her own health care. The evidence Plaintiff has uncovered establishes that is exactly what happened in this case.

B. The "OCS Heart" technology

As part of its campaign to improve its heart transplant numbers, Mayo embraced a technology called the "Organ Care System (OCS) Heart." This machine, designed and sold by a company called TransMedics, is colloquially known as the "heart in a box." It allows a transplant program to accept donor

[3] All references to "Ex. __" refer to the Exhibits to the Declaration of Brandon Thompson being filed contemporaneously with this brief.

hearts from much longer distances, because rather than being kept "on ice" the donor heart is maintained in a beating state on the OCS machine. Ex. F ("OCS Manual") at 20.

As part of obtaining FDA approval for the OCS Heart, TransMedics was required to first study the device's performance. The three key studies are referred to as "PROCEED II" (conducted between 2008 and 2013), "Heart EXPAND" (conducted between 2015 and 2020), and "EXPAND Continued Access Protocol" ("CAP," an extension of the EXPAND study). The study findings relevant to this motion are as follows:

- In PROCEED II – the only study comparing OCS to standard cold storage – researchers found that "overall survival was lower in patients transplanted with DBD[4] hearts preserved with the OCS Heart System compared to patients transplanted with donor hearts preserved with cold static preservation." OCS Manual at 11.

- Across studies, "[p]athological evidence of myocardial injury has been observed in some turned-down DBD hearts preserved with the OCS Heart System. It is unknown whether the injury was due to the use of the OCS Heart System." OCS Manual at 10-11.

[4] When it comes to heart transplant there are two broad categories of donor hearts: "DBD" (donation after brain death) and "DCD" (donation after circulatory death). A DBD heart has usually not experienced any prolonged period of cardiac arrest, while a DCD heart has by definition stopped beating. This case only involves DBD hearts.

- In the EXPAND trial, 18 of the 93 hearts "did not meet transplantability criteria following preservation on OCS Heart System." OCS Manual at 135. In other words, nearly 20% of the hearts had to be discarded after they came out of the machine and the transplant surgeons inspected them. OCS Manual at 126. In the CAP trial, 4 of the 45 hearts – nearly one in ten – were discarded after being preserved on OCS. OCS Manual at 140.

- Putting these statistics together, 22 out of 138 hearts – 16%, or nearly one out of every six hearts preserved using OCS – had to be discarded once they came out of the machine and were inspected.

Though the technology was promising overall, the specific findings outlined above were quite concerning. When the FDA panel considering approval of the OCS Heart met in April 2021, there was hot debate over whether the benefits of the machine outweighed the risks. Dr. Andrew Farb, Chief Medical Officer in the Office of Cardiovascular Devices at FDA's Center for Devices and Radiological Health, made a detailed presentation outlining his concerns about the suspicious injuries that had been observed in certain OCS hearts. When looking under a microscope he had found "severe and extensive ischemic injury" in many of the hearts that had been preserved and transported on OCS; in his testimony to the FDA panel he explained that "the findings show, in most cases, that the OCS system did not provide effective organ preservation or that its use caused severe myocardial damage." Ex. H ("FDA Minutes") at 8. Other panelists (and members of the public) expressed serious concerns about the device as well. *See* FDA Minutes, generally.

The panel ultimately voted for approval, albeit with numerous dissenters. FDA Minutes at 20-22. But the concerns prompted TransMedics to provide a host of warnings and directions to institutions using OCS. This includes the following:

1.5. Warnings

- **The OCS Heart System is not intended for the preservation of donor hearts deemed suitable for procurement and transplantation using cold static cardioplegic preservation techniques (e.g., ≤4hours of cross-clamp time). In the PROCEED II randomized controlled trial, survival was lower in patients transplanted with DBD donor hearts preserved with the OCS Heart System compared to patients transplanted with donor hearts preserved with cold static preservation.**

- Pathological evidence of myocardial injury has been observed in some turned-down DBD hearts preserved with the OCS Heart System. It is unknown whether the injury was due to the use of the OCS Heart System. The transplant turn-down rate of post-preservation donor hearts is higher after OCS Heart System preservation than after cold static preservation.

1.7. Patient Counseling

Physicians should review the following information when counseling patients about the TransMedics Organ Care System (OCS) Heart System:

...

- Physicians and patients should be aware that in the historical PROCEED II randomized controlled trial conducted between 2008-2013 with an earlier design iteration of the OCS Heart System, which studied standard donor hearts suitable for cold static cardioplegic preservation, overall survival was lower in patients transplanted with DBD hearts preserved with the OCS Heart

System compared to patients transplanted with donor hearts preserved with cold static preservation (see Appendix C for additional details). PROCEED II was the only randomized controlled trial comparing the safety and effectiveness of DBD heart preservation using the OCS Heart System to that using cold static storage.

...

- In cases in which transplantation with an available DBD donor heart would require prolonged cold static cardioplegic preservation, patients and physicians should consider the benefits and risks of proceeding with heart transplantation using the OCS Heart vs. the risks associated with waiting for a DBD donor heart that would not require prolonged cold static cardioplegic preservation.

OCS Manual at 10-12 (bolding in original). TransMedics also directs institutions like Mayo to provide patients with "the OCS Heart System Patient Brochure that describes the device, the benefits and risks, and provides an overall summary of the clinical experience with the OCS Heart System." OCS Manual at 11.

Despite TransMedics' warnings and its guidance about what should be shared with patients, Mayo as a rule does not share any of that information with its patients. In fact, Mayo misleads patients about the results of the studies and the efficacy of the OCS. Villavicencio Dep., 138:21-145:15. Mayo also does not provide patients with a copy of the OCS Heart System Patient Brochure. *Id.*, 143:12-17; Rosenbaum Dep., 28:6-21.

There is no evidence that Noah Leopold or his family was ever told a single thing about the OCS. In fact, despite the warnings and directions from the

manufacturer about "patient counseling," Noah and his family were never even told the machine was going to be used at all.

C. Noah Leopold and his cardiac history

Noah Leopold was a forty-year-old accountant and lawyer from Florida who had longstanding heart issues stemming from chemotherapy treatment he received for childhood cancer. When he was thirteen his doctors told him he would likely need a heart transplant someday, and he spent most of his adult life preparing for that eventuality. He started treating with cardiologist Dr. Barry Boilson at Mayo in 2014 – while his initial evaluation was concerning, in July 2014 a full workup revealed he was "too well for a transplant." Boilson Dep., 12:1-10. He continued to follow up at Mayo, often multiple times per year, and up until late 2022 or early 2023 "remained amazingly stable." *Id.*, 12:13-21. He did everything his doctors asked, and was "as close as you could describe to a model patient." *Id.*, 15:12-21.

In early 2023 Noah's heart function had worsened to the point that his doctors were concerned the time for a transplant had come, although he was still well enough to wait until August to have a full workup at Mayo. *Id.*, 19:19-21:5. The workup confirmed the need for a transplant; he was admitted to the hospital, and put on the transplant list.

D. Mayo's representations to Noah

Noah had graduated *summa cum laude* (while in heart failure, no less) and scored in the top 1% of all examinees on the Florida bar exam. Between that education and his natural inquisitiveness, he was well-known at Mayo for asking more questions and being more involved in his own care than just about any other patient. Boilson Dep., 15:15-21; 8:17-9:5; Rosenbaum Dep., 9:8-10:9. When Noah had his first call with Mayo's pretransplant coordinator, he asked more questions than any of the roughly two hundred patients the coordinator has ever dealt with. Prince Dep., 17:17-17:11. When he had his pre-transplant psychiatric consult (a required part of any transplant operation), the team noted the following:

> Accustomed to being a productive, take-charge individual, he will may [sic] find the loss of autonomy and heightened dependency that occurs in the hospital taxing. **Accordingly, any time he can be given a choice, even about the most mundane details of his daily routine, I think this will be helpful** as it will give him some sense of agency and independence, both of which he will need to persevere productively in the days ahead.

Ex. L at 1573 (emphasis added).

Dr. Boilson testified this need to be involved in "every mundane detail" was "absolutely consistent" with the Noah he knew. Boilson Dep., 70:1-7. And

[redacted] acutely felt by every doctor who encountered him – starting with his initial admission.

When Noah was admitted to Mayo for his transplant, one of the first doctors he spoke to at length was cardiac intensivist Bradley Ternus. Noah and his family asked Dr. Ternus a long list of questions about the transplant process, timing, donor risk factors, and the like. [redacted] One of the things Noah specifically asked about was the possibility that the donor heart might come from someone who had died of a drug overdose:

> Somebody told me – I have, you know, I have a legitimate question about the ODs – drug overdose patients, because, you know, like, I'm not in immediate – I'm not, like, I have a lot of health issues besides my heart, and I, we don't know it could play, I mean, with other organs. I'm glad that I'm not desperate either.

[redacted].[5] Dr. Ternus assured Noah that a heart from a donor who had died of a drug overdose would be considered "high risk," and that although such a heart could still be usable, the Mayo team wouldn't accept such a donation "without conversation":

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[5] Noah's mother Karen recorded the discussion on video as a substitute for taking notes, because she was afraid she wouldn't recall the details later. K. Leopold Decl. at ¶ 3. The entire video of the conversation between the Leopold family and Dr. Ternus was played during Dr. Ternus' deposition, creating a transcript of it.

> Generally, they don't accept donations from high-risk donors without conversation, so… when it comes down to that, you will be involved in that conversation. Um, you know, anyone who's, you know, had a drug overdose or something like that is considered a high-risk donor just because of their lifestyle. Um, but just because he's considered a high-risk donor, doesn't meant that there's anything wrong with the heart…. A lot of it comes down to the transplant team. And the transplant team knows you well. They're not going to take a marginal heart.

[redacted]. Noah asked Dr. Ternus what he meant by "marginal heart," and Dr. Ternus explained that because Noah had "the luxury of time," the transplant team was waiting for "the perfect heart":

> They're not going to take a marginal heart. You know, there are times we will take one that's kind of marginal because it's – you know, it's a 65-year-old who's very sick and we just need to give him what – like you said. But if you're otherwise, you know, functioning, like, we can – **we have the luxury of time in waiting for a good one**. So, and the transplant team knows that, so, uh, there are times where they're getting offers and they turn them down, and they won't even talk to you. Cuz they're like, eh, it's marginal, **we won't accept it, we want an—or you know, perfect one. If it's not that, we want to get you the perfect one**, so, um, the transplant team knows that.

[redacted]

Noah and his family were of course pleased to know he had the "luxury of time," and that Mayo was planning to accept nothing less than "the perfect heart" for him. And when they heard on August 17 (the day after he was admitted) that a heart was available, they were ecstatic. Later that day, Noah and his parents met with Mayo cardiothoracic surgeon Dr. Philip Spencer to walk through the transplant process. Noah asked Dr. Spencer about the donor's medical history, age, history of drug use, and where the heart was coming from. N. Leopold Decl. at ¶ 6. Dr. Spencer told them he could not disclose that information – all he was willing to share was that the heart "was in good condition." *Id*.

Noah then asked Dr. Spencer questions about the procedure itself. He explained the procedure, and then "was very specific" when he told Noah and his parents "that [Noah's] heart would not be explanted until the donor's heart was examined in the OR and confirmed to be suitable for transplant." *Id*. Norman and Karen, in updating friends and family about the availability of a heart for Noah, sent emails and text messages confirming this specific plan. *See, generally,* Ex. R. Unfortunately, lab tests showed some (temporary) issues with Noah's kidney function and the transplant had to be postponed.

Another heart – the donor heart at the center of this case – became available on August 29. Cardiologist Dr. Andrew Rosenbaum was responsible

for obtaining Noah's informed consent for the procedure. Dr. Rosenbaum testified that Noah was one of the most "inquisitive" patients he had ever encountered. Rosenbaum Dep., 9:8-10:9.

The organ transplantation system in the United States is managed by an organization called the United Network for Organ Sharing, or "UNOS." UNOS gathers extensive medical and social information about potential organ donors, then makes that information available to transplanting institutions considering an organ "offer" for one of their patients. The transplanting institution is responsible for reviewing that information as part of determining whether an organ is suitable for a particular patient. The UNOS records for this donor were available to Mayo – including Dr. Rosenbaum – as part of providing informed consent to Noah. *Id.*, 55:23-56:10. The records provided the following information about the donor:

- He had died of an intracranial hemorrhage brought on by a meth overdose;

- He had amphetamines, cannabis, buprenorphine, fentanyl, MDA, and methamphetamine in his system at the time he died;

- He was forty-two years old, and had been incarcerated for approximately twenty of those years;

- He used IV and inhaled meth on a weekly basis for the last six years;
- He was a pack-and-a-half-a-day smoker;
- He had a history of alcoholism;
- He had had prior cardiac surgery to repair a "hole in his heart."

Ex. K at UNOS 0031-0032, 0040, 0184. Dr. Rosenbaum did not share any of that information with Noah. Instead, he merely told Noah the donor was a "risk criteria" donor, which meant he had "certain characteristics that might increase their risk of having HIV, hepatitis C or B." Rosenbaum Dep., 61:19-65:15; Simha Decl. at 12. He did not give Noah any specifics about what those "characteristics" might be. *Id*., 63:12-18. But he reassured Noah that any "risk" was very small because the donor had been carefully screened for those viruses. *Id*., 64:25-65:4. Simha Decl. at 12.

Even with this limited information, Noah was quite hesitant. He first spoke with his wife, who asked if there was "anything specific" about the donor that was concerning. Noah responded that there wasn't, "but if he had anything bad they would not be recommending the heart for [me]." Simha Decl. at 12. Noah then got his sister Jenna on the phone as well. As Jenna puts it, Noah "was

terrified of receiving the heart of a drug addict, criminal, or someone with a troubled history." J. Shulman Decl. at ¶ 5.

Later that day Noah had another discussion with Dr. Rosenbaum, with his parents in the room and Jenna on the phone. In response to Noah's hesitations, Dr. Rosenbaum told the family this:

> Noah—I know this is not an easy decision for you to make. But I believe that this is your heart. This is the heart that was meant for you, Noah. This is a perfect heart. This is the heart I would transplant to my mother, father, sister, brother, etc.

J. Shulman Decl. at ¶ 6; *see also* K. Leopold Decl. at ¶ 5, N. Leopold Decl. at ¶ 7; Simha Decl. at ¶ 14.

Noah had "stressed the importance repeatedly of getting a heart from a young healthy donor," and was willing to wait if necessary. Simha Decl. at 12. Mayo had now told him he had "the luxury of time," that it would not accept a heart from a drug overdose donor without having a conversation with him about it first, that it would accept nothing less than "the perfect heart," and that this was indeed that "perfect heart." With those assurances, he agreed to go forward with the procedure.

Dr. Rosenbaum knew Mayo's plan was to transport the donor heart on OCS. Rosenbaum Dep., 60:6-61:18. But he did not tell Noah anything about OCS, nor did he share the OCS patient safety brochure with him. *Id.*, 28:6-21.

Dr. Villavicencio was to be the surgeon for Noah's transplant, and later that afternoon he went to see Noah and his father. He knew all about the donor's medical and social history. Villavicencio Dep., 42:7-20. But he didn't disclose any of it to Noah. Instead, he simply told Noah the heart was coming from an "excellent donor." *Id*., 60:22-61:3.; Simha Decl. at 12.

Dr. Villavicencio also knew that the donor had died of an intracranial hemorrhage, which had been caused by the meth overdose. *Id*., 42:17-20. As chance would have it, Dr. Villavicencio and his Mayo colleagues had published a study just over a year before Noah's attempted transplant, the purpose of which was to "determine if recipients of donors who die due to intracranial hemorrhage have worse outcomes post heart transplant." Ex. P. Dr. Villavicencio and his colleagues concluded that they did indeed have worse outcomes. In fact, the title of their study was "Heart Transplant Recipients of Donors with Intracranial Hemorrhage Have Worse Survival." But Dr. Villavicencio mentioned none of this to Noah – again, he simply told him the donor was "excellent."

Dr. Villavicencio knew the plan was to transport the donor heart on OCS, and he knew all about the results of the OCS studies. Villavicencio Dep., 138:23-145:15. But he told Noah nothing – nothing about the reduced survival statistics, nothing about the mysterious myocardial damage OCS hearts were known to suffer, and nothing about the one-in-six chance the heart would have to be

discarded once it was inspected in the operating room. And Dr. Villavicencio did not tell Noah that – contrary to what Dr. Spencer had promised – his plan was to remove Noah's heart before the donor heart even arrived at the hospital.

E. The transport and the failed transplant attempt

As part of its push to increase transplant numbers, starting in early 2022 Mayo hired three "procurement" surgeons whose job is almost exclusively to go and obtain hearts. Knop Dep., 6:9-16; Altarabsheh Dep., 11:11-12:24. Dr. Knop and Dr. Altarabsheh were the two surgeons assigned to the "procurement run" for Noah's donor heart. They were accompanied by two OCS specialists (Danielle Fay and Megan Osterhaus), whose job was to operate the OCS machine, and a monitor technician (Michael Pick). The team flew to Idaho, where the surgeons physically removed the heart from the donor's chest. It was then attached to the OCS, which was loaded onto the airplane, and the team returned to Minnesota.

One of the key features of the OCS is that the heart function is continually monitored during transport. *See, generally*, OCS Manual at 20. This involves both drawing and analyzing blood samples from the heart, and subjectively looking at the function of the heart through a clear window on the machine. Of course, for such monitoring to be effective "somebody's got to be actually looking at that

stuff and doing an ongoing assessment of the heart." Altarabsheh Dep., 110:17-115:7.

The procurement surgeons – in this case Dr. Knop and Dr. Altarabsheh – are responsible for "assess[ing] the heart visually during the flight, at the end of the flight, in many occasions visually." Knop Dep., 65:7-12. As established by the studies of the OCS's performance, the heart function can and does change during transport on OCS. Altarabsheh Dep., 113:14-17. This is one of the reasons the machine has a clear window, and "an important part of the ongoing assessment of the heart" is to look at the heart "to see if it still looks like it's functioning well." *Id.*, 114:8-24.

[redacted] But the surgeons didn't notice, and the technician didn't seem to appreciate the significance of these findings, because no one alerted the transplant team in Rochester that the heart was "not

robust" during transport. Villavicencio Dep., 27:6-10. Dr. Villavicencio would have wanted to know that, of course; given his plan to remove Noah's heart before the donor heart arrived, if a problem with the donor heart wasn't noticed until it got to the operating room it would be too late. *Id.*, 27:20-28:20.[6]

Once the heart did arrive, Dr. Villavicencio noted that there was "bruising" and "[t]he heart was large with a significant size mismatch" between the donor heart and the space in Noah's chest – it was thirty percent larger. Ex. M at 2130; Villavicencio Dep., 39:8-40:11. This could be an issue, because "[s]ize mismatch of greater than 20 percent is generally associated with worse outcome." Rosenbaum Dep., 51:23-52:5. No one from Mayo had done anything to calculate whether there would be a size mismatch, even though UNOS provides

a calculator allowing doctors to do exactly that. *See* https://insights.unos.org/phm-calculator/.

But all of that was a moot point, because Noah's heart had already been removed and so the transplant had to go forward regardless of how bruised, "not robust," or oversized the donor heart was. Dr. Villavicencio performed "surgical maneuvers" to make the heart fit as best he could, which he thought led to a "good result." Ex. M at 2130. But when he tried to restart the heart, it began to bleed uncontrollably. Dr. Villavicencio tried to place several sutures, but the heart "bled more and started falling apart." *Id*. at 2131. The surgeons "tried several hours to stop the bleeding but it was a futile effort." *Id*. The only way to stop the bleeding was to remove the diseased donor heart, leaving Noah with no heart at all. By that time the donor heart looked like one big blood clot. *Id*.

Noah was taken back to the ICU in critical condition. Dr. Villavicencio met with the Leopold family and told them there had been a "problem" with the donor heart – that it was "bruised when it came out of the box." He explained the measures he had taken, and that Noah was now without a heart, being kept alive on a bypass machine. N. Leopold Decl. at ¶ 9.

Mayo scrambled to find a new heart for Noah, but he was too sick to even attempt a transplant right away. Several days passed before he stabilized enough

for the doctors to try to place a new, better heart – which they were able to successfully do. But the repercussions of the disastrous failed transplant had taken their toll, and Noah never recovered. He passed away on September 9, 2023.

F. Mayo's ongoing concealment

Dr. Villavicencio's best hypothesis as to why the donor heart failed so catastrophically is that there was "something wrong with the heart" that caused it to experience "microscopic tears" while it was on the OCS machine, and those tears broke into widespread bleeding during the surgery. Villavicencio Dep., 93:17-95:10. In other words, "there was something about this OCS machine's perfusion that caused a catastrophic loss of this donor heart." *Id.*, 98:20-25. This is consistent with what Dr. Spencer told Noah's wife several days later: that there may have been a "technical glitch" that had to do with the way the heart was put on the OCS by the procurement surgeons. Simha Decl. at 34. Mayo acknowledges this "could have implications for the OCS." Villavicencio Dep., 97:5-8. It also acknowledges that the purpose of reporting adverse events like this one is "to get other people thinking about it in order to advance science and patient safety." *Id.*, 97:9-14.

But Mayo has not reported this incident to TransMedics, has not reported it to the FDA, has not discussed it with any of the other transplant centers that use the OCS, and has blocked its own doctors from publishing a case report that would allow others to be aware of this potential issue. *Id*., 98:11-19, 103:15-21, 101:8-15, 105:11-106:3.

Why is Mayo concealing this incident? Consistent with its ongoing efforts to bolster its reputation, Mayo is waiting for the "dust of this lawsuit" to settle, because it doesn't want "bad publicity for the transplant program." *Id*., 98:11-19, 108:6-11.

Argument

I. Plaintiff's motion should be granted if the evidence could lead a jury to find, by clear and convincing evidence, that Mayo showed deliberate disregard for Noah Leopold's rights or safety.

Under Minnesota law, punitive damages are awarded in a civil case if the plaintiff proves, by clear and convincing evidence, that a defendant acted in a manner that showed deliberate disregard for the rights or safety of another. Minn. Stat. §§ 549.191; 549.20. Meeting this standard requires a plaintiff to show that the defendant had knowledge that what it was doing created a "high probability of injury to the rights or safety of others," and took deliberate action

that showed conscious disregard of the risk of that injury or indifference to the risk of that injury. Minn. Stat. § 549.20, subd. 1(b)[7].

In deciding whether to grant leave to amend to add a claim for punitive damages, however, the bar is much lower. The trial court does not weigh the evidence or make credibility determinations; instead, the only question is whether the evidence presented would be enough to allow the plaintiff to survive a motion for a directed verdict. *Swanlund v. Shimano Indus. Corp., Ltd.*, 459 N.W.2d 151, 155 (Minn. App. 1990). This is not a difficult standard to meet: "The plaintiff is not required to demonstrate an entitlement to punitive damages per se, but only an entitlement to allege such damages." *Olson v. Snap Products, Inc.*, 29 F.Supp.2d 1027, 1034 (D. Minn. 1998). And while clear and convincing evidence is required to prevail at trial, it is not required at the pleading stage. *See Thompson v. Hughart*, 664 N.W.2d 372, 377 (Minn. App. 2003).

As outlined below, a reasonable jury could conclude that Mayo was aware it was acting in a manner that had a high probability of causing injury to Noah Leopold's rights, and did it anyway. A reasonable jury could also conclude that Mayo was aware it was acting in a manner that had a high probability of

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[7] In order for an employer like Mayo to be assessed punitive damages for the conduct of its employees, Plaintiff would ordinarily need to also meet the requirements of Minn. Stat. § 549.20, subd. 2. Mayo has stipulated that Plaintiff need not meet those requirements in this case, and has agreed to be liable for any punitive damages assessed against its employees irrespective of the requirements of subdivision 2. *See* Dkt. No. 23.

harming Mr. Leopold's safety, and did it anyway. Either of these would be enough for the Court to grant Plaintiff's motion.

II. A jury could find numerous ways in which Mayo showed deliberate disregard for Noah Leopold's rights.

In Minnesota, a patient has the right to receive any information he or she "would consider significant" in deciding whether to consent to proposed medical treatment. *Kinikin v. Heupel*, 305 N.W.2d 589, 595 (Minn. 1981); *see also* Minn. Prac. 4A, CIVJIG 80.25. Mayo's doctors concede that is how medicine is supposed to work. Villavicencio Dep., 53:19-24; Rosenbaum Dep., 29:24-30:5; Boilson Dep., 60:5-20. This is not just standard medical practice; the right is codified in Minnesota's "Patient Bill of Rights":

> Patients and residents shall be given by their physicians, advanced practice registered nurses, or physician assistants complete and current information concerning their diagnosis, treatment, alternatives, risks, and prognosis as required by the physician's, advanced practice registered nurse's, or physician assistant's legal duty to disclose. This information shall be in terms and language the patients or residents can reasonably be expected to understand. Patients and residents may be accompanied by a family member or other chosen representative, or both. This information shall include the likely medical or major psychological results of the treatment and its alternatives.

Minn. Stat. § 144.651, subd. 9; *see also* Minn. Prac. 4A, CIVJIG 80.25 use note (explaining that "Minnesota's 'Patient's Bill of Rights' sets out a statutory duty to disclose information about treatment."). Deprivation of this right to be fully

informed can and does give rise to a punitive damages claim. *See* Ex A (granting leave to pursue punitive damages claim where doctor deliberately chose not to provide information to patient, despite "knowing he was the only path to receive that information." (COL ¶ 8); Ex. B (granting leave where doctor failed communicate radiology findings); Exs. C-E, BB (granting leave where defendants engaged in conduct such as altering records, hiring unqualified and untrained personnel, using inappropriate surgical technique, performing surgery when ill, and allowing financial incentive to cloud medical judgment).

Importantly for this case, a patient's right to be informed of risks is not limited to those risks which the doctor would find significant. A patient has the right to be informed of any risks he or she would find significant. And "to the extent a doctor is or can be aware that his patient attaches particular significance to risks not generally considered by the medical profession serious enough to require discussion with the patient, these too must be brought out." *Kinikin*, 305 N.W.2d at 595.

That distinction is critical in this case, because Noah Leopold was an unusually involved patient who asked countless questions and wanted to be told about "every mundane detail" of his care. Mayo was not intending to perform a rudimentary procedure on Noah. It was planning to irreversibly remove his heart and replace it with the heart of a stranger. It is difficult to conceive of a

surgery that would carry more significance for a patient. Noah had the legal right to be fully informed about every aspect of that surgery, including both the procedure itself and the organ Mayo intended to permanently implant in his body. But as outlined below, Mayo knowingly deprived Noah of that right in numerous ways.

A. Noah had the right to know his donor had died of a drug overdose. Mayo deliberately deprived him of that right.

Mayo knew Noah didn't want to receive the heart of a drug user; [redacted] Dr. Ternus assured Noah that such a donor would be considered "high risk," that he had the "luxury of time," that Mayo intended to wait for "the perfect heart," that Mayo would not accept a "marginal heart," and that if Mayo was considering a heart from a drug overdose donor "you will be involved in that conversation." [redacted]

It was unquestionably "significant" to Noah to know whether his heart donor had had an overdose – he talked about it with both Dr. Ternus and Dr. Spencer. Under Minnesota law Noah therefore had a legal right to that information. *See Kinikin*, 305 N.W.2d at 595; *see also* Minn. Prac. 4A, CIVJIG 80.25.

Mayo admits it did not provide Noah with this information. Ex. O at No. 7. On the contrary, Mayo actively misled Noah into believing the heart had not come from an overdose donor. [redacted]

Like in the *Vasquez* case (see Ex. A), Mayo was the "only path" by which Noah could have received this information. Under these circumstances, a reasonable jury could conclude that Mayo engaged in behavior that demonstrated deliberate disregard for Noah's legal rights. On this basis alone, Plaintiff's motion to amend should be granted.

B. Noah had the right to know his donor was a drug-addicted, convicted felon, pack-and-a-half a day smoking former alcoholic. Mayo deliberately deprived him of that right.

Mayo knew Noah was concerned about the quality of the donor heart that would be transplanted into his body. As his sister puts it, Noah "was very clear that he wanted a healthy heart and was terrified of receiving the heart of a drug addict, criminal, or someone with a troubled history." J. Leopold Decl., ¶ 5. It hardly can be disputed that drug use – especially meth – is bad for the heart. *See* [redacted] Rosenbaum Dep., 71:22-72:6; 72:20-24; Boilson Dep., 72:18-

22. The same holds true for cigarette smoking and alcoholism. [redacted] Rosenbaum Dep., 72:8-15.

Mayo accepted a heart from a convicted felon, meth-addicted, pack-and-a-half-a-day smoker who had a history of alcoholism and who died with a half-dozen illegal drugs in his system. Ex. K at UNOS 0031-0032, 0040, 0184. A jury could easily conclude that Mayo knew or should have known that this information would have been highly significant to Noah. Indeed, several Mayo doctors explicitly admitted as much. *See* [redacted] Rosenbaum Dep., 46:17-47:2; 49:19-51:15; Boilson Dep., 74:16-25.

Here again, Mayo was the "only path" for Noah to receive this information, but Mayo intentionally kept it from him. Ex. O at No. 7. A jury could conclude that by concealing this information from him – and furthermore by actively misleading him into believing this heart was "perfect" and coming from an "excellent donor" – Mayo deliberately disregarded Noah's legal rights.

C. Noah had the right to know his donor had experienced an intracranial hemorrhage. Mayo deliberately deprived him of that right.

Mayo knew – because its doctors had published a study on the topic – that "Heart Transplant Recipients of Donors with Intracranial Hemorrhage Have Worse Survival." Ex. P. Because of this, "all things being equal, we would prefer

for the donor to not have died of an intracranial hemorrhage." Rosenbaum Dep., 72:16-19.

The donor in this case died of an intracranial hemorrhage brought on by a meth overdose. A reasonable juror could easily conclude that Noah would have found that information to be significant as he considered whether to accept the heart; an obvious fact that, here again, more than one Mayo doctor has admitted. Rosenbaum Dep., 46:17-49:12; [redacted]

But yet again, Mayo – despite knowing it was the only path for Noah to receive that information – did not provide it to him. Ex. O at No. 7. A jury could conclude that this information – that the donor had had an intracranial hemorrhage, and Mayo's own doctors had concluded that "heart transplant recipients of donors with intracranial hemorrhage have worse survival" – would have been significant to Noah. That same jury could find that concealing this information from Noah was yet another example of a deliberate disregard of his rights.

D. Noah had the right to know about the risks associated with using the OCS Heart for transport. Mayo deliberately deprived him of that right.

As outlined above, some of the risks of OCS include the fact that patient survival is lower, that some hearts are mysteriously damaged and the machine

may be the culprit, and that there is a nearly one in six chance that something will happen during transport to render the heart unusable. *See* pp. 6-10, *supra*. These are not trivial risks; on the contrary, they are so significant that they led the FDA's Chief Medical Officer for Cardiovascular Devices to testify "the findings show, in most cases, that the OCS system did not provide effective organ preservation or that its use caused severe myocardial damage." Ex. H (FDA Minutes) at 8.

Given the nature of the risks, and given that the manufacturer explicitly directs physicians to discuss those risks with patients, a jury could easily conclude that Noah would have found them significant and that he therefore had a right to this information. More than one Mayo physician admitted as much. *See* Rosenbaum Dep., 29:23-33:13, 36:6-11, 39:25-40:13, 42:7-11; [redacted]

[redacted]

But the undisputed evidence is that no one at Mayo ever even mentioned the use of OCS to Noah, let alone discussed any of the risks. Noah of course had no way of knowing about the plan to use OCS if Mayo didn't tell him. And a jury could easily conclude that in concealing this information from Noah, Mayo deliberately disregarded his right to know critically significant information. This is particularly true, as discussed below, in the specific context of this case.

E. Particularly given the use of OCS, Noah had the right to know that Mayo was planning to remove his heart before the donor heart arrived. Mayo deliberately deprived him of that right.

One of the most significant risks of OCS is that the heart will be rendered unusable during transport, and the procedure will need to be aborted after the surgeon has a chance to take the heart out of the machine and inspect it. As outlined above, this happened with nearly one out of every six hearts in the device trials. This is no doubt why the OCS Patient Brochure (which Mayo never gave Noah, *see* Rosenbaum Dep., 28:6-21) contains the following under "Potential Risks Associated with OCS Heart":

> It is possible that after preservation on the OCS Heart, your doctor may decide that the donor heart is not good enough to be transplanted. If this happens, your transplant surgery may be cancelled, and you will retain your status on the heart transplant waiting list for another donor heart to become available.

Ex. G (OCS Brochure) at 6. Given the one-in-six risk that the OCS-transported heart will become unusable, it would seem patently obvious that the surgeon shouldn't take the irreversible step of removing the patient's native heart until the donor heart has arrived, been taken out of the OCS, and undergone careful inspection. That is the way it is done at Mayo Jacksonville. Ex. Q at 4 (explaining that the heart is "reassessed" once it "reaches the recipient OR on the OCS machine," and that only after "if it is decided to proceed with the transplant"

will the procedure go forward); *see also* Villavicencio Dep., 31:18-32:18. And that is how Mayo told Noah and his family it would be done in this case. N. Leopold Decl. at ¶¶ 6, 8.[8]

But that is not what Mayo did, and – unbeknownst to Noah and his family – not what it ever planned to do. Instead, the plan was for the Mayo team to irreversibly remove Noah's native heart as soon as the airplane with the OCS machine landed in Rochester, but before the donor heart arrived at the hospital and could be inspected. Villavicencio Dep., 27:11-29:17. Given the published statistics, this meant there was a one-in-six chance that the donor heart would be unusable and Noah would have been left without a functioning heart because his native heart had been irreversibly removed. Which, tragically, is exactly what happened and ultimately why Noah died.

A jury could easily conclude that this information would have been significant to Noah in deciding whether to consent to Mayo's plan. But Mayo concealed that plan from him. A jury could conclude that in doing so, Mayo deliberately disregarded Noah's right to have significant information.

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[8] Noah and his family were not told the heart would be transported on OCS. They were simply told the heart would be coming from some distance away, and that once it arrived it would be inspected by the transplanting surgeon before Noah's native heart was irreversibly removed. This is confirmed not only by the family's testimony, but also by contemporaneous texts and emails the family sent. *See* Ex. R.

F. Particularly given the use of OCS, Noah had the right to know that the donor's family reported a history of prior cardiac surgery. Mayo deliberately deprived him of that right.

One of the considerations for a donor heart is whether the donor had prior heart surgery. [redacted] Villavicencio Dep., 66:1-67:5. [redacted] *Id.*, 67:6-18. Doctors are explicitly warned to not use the OCS under certain conditions, including those involving an unrepaired "hole in the heart":

> **1.4. Contraindications**
>
> Do not use the OCS™ Heart System if any of the following conditions exist:
>
> - Moderate to severe aortic valve incompetence in donor heart
> - Observed myocardial contusion on donor heart
> - Known unrepaired interatrial or interventricular defects including patent foramen ovale.

OCS Manual at 10.

Whether this donor had had a "hole in his heart," and whether it had been repaired, was therefore significant for two reasons: if there was a "hole" that had

previously been repaired, there was a risk the donor heart had been damaged during that repair. If the hole had not been repaired, the heart should never have been transported on OCS at all.

At the time Noah consented to the transplant, [redacted] Villavicencio Dep., 69:18-23; Ex. K at UNOS 0184. In addition to having this history, Mayo knew the heart was going to be transported on OCS. Noah could not possibly have gotten this information from any source other than Mayo. But Mayo concealed it from him. Villavicencio Dep., 71:16-23.

[redacted] *Id.*, 72:1-73:2. This of course meant that Mayo deliberately disregarded the donor's reported medical history; moreover, given the risk of heart damage and the risks of using OCS, a jury could easily conclude that Noah had a right to know that the donor's family had reported a history of heart surgery. This is yet another way a jury could find that Mayo deliberately disregarded Noah's rights.

G. The fact that Mayo claims it has a justification for deliberately concealing significant information from Noah is irrelevant to this motion.

Mayo's doctors were of course deposed at length about all the issues outlined above. Their responses took one of two forms. Some of the doctors claimed (against all logical evidence) that Noah wouldn't have found any of the information all that significant, and so it was appropriate for it to be concealed from him. Others admitted (usually only after a great deal of resistance) that Noah would probably have found the information significant, but that Mayo was "prohibited" from giving it to him. Neither of these justifications are remotely persuasive (or even close to true), but more importantly neither of them have any relevance to the present motion.

1. A reasonable jury could easily find that the information Mayo concealed from Noah would have been "significant" to him, and that he therefore had a right to it.

With respect to the claim that Noah would not have found the information outlined above to be "significant," such a claim is absurd on its face. Here is an example of the lengths to which some Mayo witnesses went to resist admitting the obvious:

Q: Okay. Let's try to put a bunch of things together then and we'll see if we can short circuit this. I want you to conjure up Noah in your mind, thoughtful, inquisitive, smart, concerned with every mundane

detail any time he can be given a choice even about the most mundane detail. Got him in your mind?

A: Yes.

Q: All right.

A: Sure.

Q: Now I want you to envision you or some other doctor telling him this: "Noah, we found a heart for you. The heart is coming from the other side of the country. We're going to bring it to you in a box. The research on this box says that one out of every five of the hearts that we transport on this box actually don't end up being suitable for transplantation. And we're going take your heart out before that heart arrives, so if it's one of those one in five then we're really in deep trouble. Oh, by the way, the heart is coming from a guy who was a meth addict, who used IV and smoked meth weekly at least for the last six years, he was a former alcoholic, smoked a pack and a half of cigarettes a day, convicted felon who was in prison for 20 years. He had meth, MDMA, fentanyl, and weed all in his system on the tox screen in the hospital. Oh, and by the way, he's a lot bigger than you, and so his heart is probably significantly bigger than your heart." Do you think Noah would have had some questions about that?

…

A: You're describing a scenario that would not happen, because most of those things are not disclosable information based on the OPTN recommendations.

Q: That's actually not true, and that's -- but that's fine. I'm not talking about that. Set aside whether you think they're disclosable. Set aside whether you think those things were clinically relevant. None of that is my question. My question is: If presented with that set of facts, can't you agree that the smartest, most thoughtful, most inquisitive patient you ever had who was concerned with every mundane detail would have at last been given pause?

A: I can't agree to that.

Boilson Dep., 83:15-85:16. Any jury could – and almost certainly would – find this testimony incredible. As outlined previously, Mayo's own providers documented that Noah wanted to be told of "every mundane detail," and that he asked more questions than any other patient. His family will testify unequivocally that he would have found the information that was concealed from him to be significant. And this testimony will be corroborated by other, less intransigent Mayo witnesses. *See, e.g.*, Rosenbaum Dep., 29:23-33:13, 36:6-11, 39:25-40:13, 42:7-11, 43:5-18, 46:17-47:2, 47:20-49:12, 49:19-50:5, 50:6-15, 52:19-53:5;

[redacted]

At the end of the day, of course, in the context of this motion weighing the credibility of the various competing testimony would be inappropriate. *Swanlund*, 459 at 155; *Olson*, 29 F.Supp.2d at 1034; *Thompson*, 664 N.W.2d at 377. And regardless of whether some Mayo witnesses try to deny it, there is absolutely no question that the evidence uncovered in this case would allow a reasonable jury to conclude that Noah had a right to the plethora of information Mayo deliberately kept from him.

2. Mayo's claim that it was "prohibited" from sharing significant information with Noah is both irrelevant and inaccurate.

Despite the (rather unbelievable) assertions of some of its employees, at the end of the day Plaintiff believes it is unlikely Mayo will claim the information outlined above would have all been completely "insignificant" to Noah. Frankly, it seems difficult to believe that anyone would try to argue that with a straight face. Instead, Mayo's primary justification for withholding the information from Noah seems to be its claim that it was "prohibited" from sharing it because of "donor privacy." Ex. O at Nos. 7 and 8; *see also* Rosenbaum Dep., 79:17-80:9. When asked to explain the source of this "prohibition," Mayo and its employees pointed to "guidance" from the Organ Procurement Transplantation Network (commonly referred to as "OPTN"). Ex. S; Villavicencio Dep., 50:11-52:11; Boilson Dep., 88:24-89:10.

In the first place, "guidance" from an organization does not and cannot trump Minnesota law. Under black-letter Minnesota law, a patient has the right to receive information that would be significant to him in making his healthcare decision – regardless of whether it is significant to the doctor, regardless of whether doctors usually disclose such information, and regardless of what the OPTN or any other organization says. *See Kinikin*, 305 N.W.2d at 595; Minn. Prac. 4A, CIVJIG 80.25. Revealingly, every Mayo employee who was questioned about that general concept acknowledged that is the way informed consent is supposed

to work. Villavicencio Dep., 53:19-24; Rosenbaum Dep., 29:24-30:5; Boilson Dep., 60:5-20. It is up to the patient – not the doctor – to decide what is significant. Whether Mayo or some other organization created an internal policy that violates Minnesota law is irrelevant to the question of whether Mayo deliberately withheld information Noah had a right to receive.

Even if the OPTN guidance were relevant, however, Mayo's reliance on it is wholly misplaced. Because that guidance explicitly recognizes it is subordinate to the legal informed consent process:

> Deceased donor information routinely shared with the recipients/ recipient families **should be limited to information required as part of the recipient informed consent process for transplantation**. This information should never make it possible to identify the donor and should not include geography information (either the donor's place of residence or hospital where donation took place), specific age or circumstance of death **unless the information is clinically relevant to the transplant recipient informed consent discussion**.

Ex. S at 2 (emphasis added). As discussed at length above, in Minnesota information is "required" and "clinically relevant" to an informed consent discussion if a patient would find it significant – regardless of whether the doctor would normally share it. The sad reality of this case is that Mayo could easily have provided Noah with the information he had a right to have, while simultaneously following the OPTN's guidance.

It is important to note that the goal of the OPTN guidance is to protect donor anonymity. Mayo could have provided Noah with all the significant information about OCS without mentioning one word about the donor. And Mayo could have provided Noah with all the significant information about the donor's medical and social history without creating any risk whatsoever that he would be identified. Saying "the donor is a meth addict who died of a meth overdose that caused an intracranial hemorrhage" would describe at a minimum hundreds of thousands of people in the United States. Adding "he was also a pack-and-a-half a day smoker and had a history of alcoholism" would certainly contribute nothing in the way of identification. And when pressed to explain how sharing that limited (yet highly significant) information with Noah could possibly have risked identifying the donor, no one at Mayo could give a coherent answer – despite trying mightily to do so. Rosenbaum Dep., 96:10-107:11; Boilson Dep., 88:6-95:6; Villavicencio Dep., 130:24-138:20.

At the end of the day, Mayo can (and no doubt will) raise "donor anonymity" concerns and "OPTN guidance" as a defense to Plaintiff's claims. But at this stage, those defenses are irrelevant. The only question is whether a jury could conclude, taking the evidence in the light most favorable to Plaintiff, that Mayo deliberately disregarded Noah's right to receive information. The answer to that question is yes, and Plaintiff's motion should therefore be granted.

III. A jury could find numerous ways in which Mayo showed deliberate disregard for Noah Leopold's safety.

In addition to awarding punitive damages for Mayo's deliberate disregard of Noah's legal right to significant information, a jury could also award punitive damages for Mayo's deliberate disregard of a substantial risk to Noah's safety. This is yet another reason Plaintiff's motion should be granted.

A. A jury could conclude that Mayo deliberately disregarded Noah's safety because it removed Noah's heart before the donor heart could be inspected.

As outlined above, there was about a one-in-six chance that the donor heart would not be suitable for transplant when it came out of the OCS machine. This heart was "not robust" and "not happy" during transport (more on that below), and when it was removed from the machine it was much too large and it was bruised. Villavicencio Dep., 39:17-42:2. But at that point Noah's native heart had already been irreversibly removed, so there was no option except to move forward with the transplant. And when the Mayo doctors did so, the heart began uncontrollably bleeding and "fell apart." Mayo's best hypothesis as to why that happened is that there was "something wrong with the heart" that caused it to experience "microscopic tears" while it was on the OCS machine, and those tears expanded into widespread bleeding during the surgery. *Id.*, 93:17-95:10; *see also* Simha Decl. at 17, 34; N. Leopold Decl. at ¶ 9.

According to TransMedics, if a donor heart ends up being unsuitable for transplant once it comes off OCS the surgery can be cancelled and the patient can go back on the waiting list. Ex. G (OCS Brochure) at 6. But that wasn't an option for Noah, because Mayo had irreversibly removed his heart before the bruised, too large, "not robust" donor heart could be inspected.

Despite Mayo's new attempts to rewrite the facts of this case, a jury could easily conclude that Mayo removed Noah's native heart before the donor heart arrived. And that same jury could easily conclude that in doing so, thereby disregarding the one-in-six chance that the heart would be unusable and a disaster would ensue, Mayo showed deliberate disregard for Noah's safety.

B. A jury could conclude that Mayo deliberately disregarded Noah's safety because it did not assess the size mismatch between Noah and the donor heart.

One of the important parameters for selecting an appropriate heart is size. The reason for this is obvious and logical: if a donor heart is much smaller than the recipient's, it will not have enough "horsepower" to run the body. If a donor heart is much larger than the recipient's, it will have to be "squeezed" into the chest cavity. This is why "[s]ize mismatch of greater than 20 percent is generally associated with worse outcome." Rosenbaum Dep., 51:23-52:5.

UNOS provides a "predicted heart mass ("PHM") calculator" that allows physicians to determine if there is a donor-recipient size match. But no one from Mayo ever performed any PHM calculation of any kind – whether using the UNOS calculator or any other resource.[9] If someone had, they would have determined that the donor heart was predicted to be almost thirty percent larger than Noah's. *See* Ex. J (completed PHM calculations). This is exactly what Dr. Villavicencio found when he opened the OCS and removed the donor heart. Villavicencio Dep., 39:8-40:11.

This dramatic size mismatch – "generally associated with worse outcome" – would of course have been significant to Noah and he had a right to know it. Rosenbaum Dep., 52:19-53:5. No one from Mayo bothered to get that information, so they could not have deliberately concealed it from him. But a jury could conclude that Mayo's failure to perform a PHM calculation – when they knew a significant size mismatch is associated with worse outcomes – showed deliberate disregard for Noah's safety.

[9] In addition to asking about this in depositions, Plaintiff served RFPs asking Mayo to produce all such calculations. Nothing was provided.

C. A jury could conclude that Mayo deliberately disregarded Noah's safety because the doctors who were supposed to be monitoring the donor heart slept through almost the entire transport.

Dr. Knop and Dr. Altarabsheh were responsible for "assess[ing] the heart visually during the flight" to ensure the heart function wasn't worsening – a known risk of OCS. They knew that "an important part of the ongoing assessment of the heart" is to look at the heart "to see if it still looks like it's functioning well." Altarabsheh Dep., 114:8-24. But they were asleep for almost the entire flight and didn't travel with the heart while it was on the ground, and therefore didn't notice that [redacted]

Given that one in six OCS hearts becomes unusable in transit, and given Mayo's plan to remove Noah's heart before the donor heart got to the OR, a jury could easily conclude that the procurement surgeons' decision to sleep through the transport showed deliberate disregard for Noah's safety.

D. A jury could conclude that Mayo deliberately disregarded Noah's safety because at least one of its technicians saw warning signs of deteriorating cardiac function and did not inform the transplant doctors.

[redacted] And her job is to watch the heart "like a hawk" during the transport. *Id.*, 30:4-21.

[redacted]

Incongruously, Ms. Fay also acknowledged the surgeons couldn't assess the heart's function while they were asleep on the plane, or while they were in a different car during the ground transport. *Id.*, 32:9-16.

Ms. Fay knew her job was to watch the heart "like a hawk," noticed potential issues with the heart function, knew the surgeons were sleeping, knew the surgeons weren't with the heart during the ground transport, and didn't raise one word of concern with anyone. A jury could easily conclude that this showed deliberate disregard for Noah's safety.

IV. Plaintiff's motion should be granted because if the jury finds for her on her battery claim, a punitive damages claim would also lie.

In addition to claims for medical negligence and negligent nondisclosure, Plaintiff has also brought a claim for battery. In Minnesota a "medical battery" claim is appropriate "when a physician fails to disclose to the patient a very material aspect of the nature and character of the operation to be performed"; put another way, when the "nature and character" of the procedure is "substantially different" than that which the patient consented to. *Kohoutek v. Hafner*, 383 N.W.2d 295, 298-99 (Minn. 1986). The underlying concept is that if the doctor performs a procedure that is fundamentally different from what the

patient understood it was going to be, he never truly "consented" to it in the first place. Battery is of course an intentional tort, and so punitive damages are generally available – an unwanted intentional physical touching by its very nature demonstrates deliberate disregard for a person's rights or safety. *See Kinikin*, 305 N.W.2d at 593 ("battery connotes an intentional invasion of another's rights, an aura of moral fault attaches, punitive damages may be available, and liability insurance coverage for the physician may be jeopardized.").

A jury could easily find for Plaintiff on her battery claim. Noah consented to this surgery on the explicit belief that Mayo had procured for him a "perfect" heart; while there can certainly be some grey area in what constitutes a "perfect" heart, a jury could certainly conclude there is a "substantial difference" between Noah's understanding of a "perfect" heart and the oversized, previously-operated-upon heart of a meth-addicted convicted felon who had died of an intracranial hemorrhage brought on by a drug overdose.

Just as important to the battery claim is Noah's ignorance of Mayo's plan for the transplant itself. When Noah consented to the surgery, he had been told by Dr. Spencer that his heart would not be removed until the donor heart – which Noah had explicitly been led to believe would not come from a drug overdose donor – had physically arrived in the operating room and been inspected and deemed suitable by the transplanting surgeon. A jury could easily

conclude that the "nature and character" of Mayo's contrary plan was "substantially different" from Noah's understanding – particularly when one considers the one-in-six chance that the donor heart would have been rendered unusable at some point on its OCS journey.

In many ways, Mayo did exactly the opposite of what it led Noah to believe it was planning to do when it obtained his "consent" for the surgery. A jury could conclude that this eliminated any consent to the procedure, thereby making what happened to Noah a battery. This is yet another reason Plaintiff's motion to add a punitive damages claim should be granted.

Conclusion

It is unclear whether Mayo's actions in this case were driven by hubris, by paternalism, or by something else entirely. But regardless of the motive, Mayo hid countless critically important facts from Noah Leopold that he had a legal right to know. It also actively misled Noah in many ways. And Mayo's actions showed a deliberate disregard for both Noah's legal rights, and his safety. For these reasons, and those discussed above, a reasonable jury could award punitive damages against Mayo. And Plaintiff's motion should therefore be granted.

Dated: October 1, 2024

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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Michelle Simha, as Trustee for the Next-of-Kin of Noah Leopold, Plaintiff, vs. Mayo Clinic, Defendant.	Civil File No. 24-CV-01097-DTS

Plaintiff's L.R. 7.1 (f)(2) Certificate of Compliance

The undersigned hereby certifies that Plaintiff's Memorandum in Support of Her Motion to Amend to Add a Claim for Punitive Damages complies with the limits of Local Rule 7.1(f) and with the type-size requirements of Local Rule 7.1(h).

This document was prepared using Microsoft Word for Office 365, and I certify that the word-count feature of the program was set to include all text – including headings, footnotes, and quotations – prior to counting the number of words in the document.

Based on the above, I certify that the document contains 11,654 words.

Dated: October 1, 2024

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